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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,403	11/27/2001	Hayat Onyuksel	27611/36927	2554

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/05/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/995,403

Applicant(s)
Onyuksel

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 14, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 6, and 10-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 6, and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other: _____

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DETAILED ACTION

1. **Applicant's election without traverse of species b (claims 5-6 and 10-12 in Paper No. 7 is acknowledged.**

Claim Rejections - 35 USC § 112

2. **The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 5-6 and 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**

Instant claims are drawn to the treatment of at least 26 disease conditions and many of which are not even connected. The causes of many of the claimed diseases are not even known and many are poorly understood (Alzheimer's for example). The active agents apparently useful in the invention as recited in the claims are "VIP/glucagon/secretin family of peptides including peptide fragments and analogs". In the paragraph bridging pages 1 and 2 of the specification, applicant lists numerous number of proteins and peptides which apparently belong to the class of this family. There is no definition or

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explanation as to what come under the category of ‘peptide fragments and analogs’ Applicant’s own statements in the specification indicates that there is an unpredictability in the art. While VIP appears to play a major role in regulating a variety of important functions and the deficiency of VIP has been linked to the pathogenesis of certain diseases, excess VIP also appears to be linked to the pathogenesis of some diseases (specification on pages 6 and 7). Instant specification provides no working examples either in vitro or in vivo for the variety of the disease conditions claimed using a variety of the active agents coming under the umbrella of VIP/glucagon/secretin family of peptides including peptide fragments and analogs’. Since there is unpredictability in the art of the treatment of the claimed diseases using the free active agents themselves, treatment of diseases using micelles containing active agents claimed is also unpredictable.

Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to specific disease(s) and specific active agent(s) disclosed as having the claimed treatment ability. It would require undue experimentation by one of ordinary skill in the art to select an active agent and practice the invention.

4.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-6 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawai (5,376,637) in combination with Trubetskoy (Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 1995) of record and either Burke (5,736,156) or EP 0 721 776 or Zhang (Internat. J. Of Pharmaceutics, 1996).

Sawai teaches that pharmaceutical composition containing VIP and a surfactant and a method of treatment of asthma (note the abstract and claim 1) What is lacking in Sawai is the specific teaching of the use of micelles containing VIP (although surfactants form micelles in aqueous solutions).

Trubetskoy discloses that polymer derivatized lipids such as PEO-phosphatidylethanolamine form micelles and such micelles can be used to solubilize poorly soluble or amphipathic substances (pages 452-453). The active agent however, was not added after the formation of micelles.

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Burke while disclosing a process of preparation of micelles and liposomes teaches that the active agent can be loaded to surfactant micelles after the preparation of the micelles (Examples 8-10).

Zhang similarly teaches that active agents such as taxol associate strongly to PEG containing polymer micelles (abstract).

EP similarly teaches that there is a electrostatic bonding when a drug is added to the macromolecular mPEG containing polymeric micelles (abstract, and examples).

The use of PEG containing polymeric compounds as the carrier of amphipathic VIP of Sawai for the treatment of asthma would have been obvious to one of ordinary skill in the art since Trubetskoy teaches that these compounds form micelles and solubilize poorly soluble or amphipathic compounds. One skilled in the art would be motivated to use this surfactant since PEG appears to increase the blood circulation time of drug carrier systems as evidenced from the teachings of Zhang (page 196, col. 1). The addition of VIP after the formation of micelles would have been obvious to one of ordinary skill in the art since the references of Burke, Zhang and EP all show that the active agent can be loaded onto the micelles; one of ordinary skill in the art would expect at least similar results.

The examiner requests copies of the references cited on 1449.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

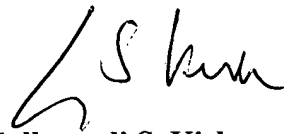
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

A handwritten signature in black ink, appearing to read 'GSK' or similar, written in a cursive style.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 25, 2003